

CLAIMS:

The current claim set of the application is presented below. Indications as to the status of the claims (“original”, “currently amended”, “cancelled”, “new”, etc.) appear in parentheses after the claim number. Deletions are identified in bold with double brackets and strikethrough (e.g. **[[deletion]]**) and new text is identified in bold with underlining (e.g. **new matter**).

1. (Original) A system comprising:
a reservoir;
a pump coupled to the reservoir;
a catheter coupled to the pump and adapted for delivering a therapeutic agent to a cerebrospinal fluid of a patient; and
an injectable gabapentin composition housed in the reservoir and deliverable through the catheter in an amount effective to treat a gabapentin-sensitive disorder in the patient,
wherein the injectable gabapentin composition comprises a pharmacologically acceptable solvent and greater than about 30 mg/ml gabapentin, and wherein the composition has a tonicity of less than about 900mOsm.
2. (Original) The system claim 1, wherein the composition is an injectable solution.
3. (Original) The system claim 2, wherein the solution comprises between about 30 mg/mL and about 100 mg/mL gabapentin.
4. (Original) The system of claim 3, wherein the solution comprises between about 30 mg/mL and about 90 mg/mL gabapentin.
5. (Original) The system of claim 4, wherein the solution comprises between about 40 mg/mL and about 90 mg/mL gabapentin.

6. (Original) The system of claim 5, wherein the solution comprises about 80 mg/mL gabapentin.
7. (Original) The system of claim 2, wherein the solution comprises greater than about 31 mg/ml gabapentin.
8. (Original) The system of claim 2, wherein the solution comprises greater than about 32 mg/ml gabapentin.
9. (Original) The system of claim 2, wherein the solution comprises greater than about 33 mg/ml gabapentin.
10. (Original) The system of claim 2, wherein the solution comprises greater than about 34 mg/ml gabapentin.
11. (Original) The system of claim 2, wherein the solution comprises greater than about 35 mg/ml gabapentin.
12. (Original) The system of claim 2, wherein the solution comprises greater than about 36 mg/ml gabapentin.
13. (Original) The system of claim 2, wherein the solution comprises greater than about 37 mg/ml gabapentin.
14. (Original) The system of claim 2, wherein the solution comprises greater than about 38 mg/ml gabapentin.
15. (Original) The system of claim 2, wherein the solution comprises greater than about 39 mg/ml gabapentin.

16. (Original) The system of claim 2, wherein the solution comprises greater than about 40 mg/ml gabapentin.
17. (Original) The system of claim 2, wherein the solvent is water.
18. (Original) The system of claim 17, wherein the solution further comprises sodium chloride.
19. (Currently Amended) The system of claim 18, wherein ~~the solution~~ the solution comprises sodium chloride in an amount such that the solution is substantially isotonic with cerebrospinal fluid.
20. (Original) The system of claim 2, wherein the solvent is sterile saline.
21. (Original) The system of claim 2, wherein the tonicity of the solution is in the range of about 250 mOsm to about 700 mOsm.
22. (Original) The system of claim 2, wherein the tonicity of the solution is in the range about 250 mOsm to about 600 mOsm.
23. (Original) The system of claim 2, wherein the tonicity of the solution is about 500 mOsm.
24. (Original) The system of claim 2, wherein the solution has a pH between about 4 and about 9.
25. (Original) The system of claim 24, wherein the solution has a pH between about 5 and about 7.

26. (Original) The system of claim 2, wherein the solution comprises substantially no preservatives.
27. (Original) The system of claim 2, wherein the solution comprises substantially no buffers.
28. (Original) The system of claim 1, wherein the injectable gabapentin composition further comprises one or more additional therapeutic agents.
29. (Original) The system of claim 28, wherein at least one of the one or more additional therapeutic agents is selected from the group consisting of:
a local anesthetic, a GABA agonist, a serotonin agonist, a thyrotropin-releasing hormone, a benzodiazepine, an opioid agonist, a non-steroidal anti-inflammatory agent, an alpha2-adrenergic agonist, an anticonvulsant agent, and an antidepressant.
30. (Original) The system of claim 28, wherein at least one of the one or more additional therapeutic agents is selected from the group consisting of:
morphine, hydromorphone, bupivacaine, clonidine, lidocaine, baclofen, muscimol, sumatriptan, sodium valproate, midazolam, adenosine, and alprazolam, or a pharmacologically acceptable salt thereof.
31. (Original) The system of claim 30, wherein the composition comprises morphine or a pharmacologically acceptable salt thereof.
32. (Original) The system of claim 31, wherein the composition comprises between about 10 mg/mL to about 50 mg/mL of the morphine or the pharmacologically acceptable salt thereof.
33. (Original) The system of claim 31, wherein the composition comprises hydromorphone or a pharmacologically acceptable salt thereof.

34. (Currently Amended) The system of claim 33, wherein the composition comprises between about 1 mg/mL to about 20 mg/mL of the hydromorphone or the pharmacologically acceptable salt thereof.[[.]]
35. (Original) The system of claim 6, wherein the solution has a pH between about 5.5 and 6.5, has a tonicity of about 500 mOsm, and comprises substantially no preservatives and substantially no buffers.
36. (Original) A system comprising:
a reservoir;
a pump coupled to the reservoir;
a catheter coupled to the pump and adapted for delivering a therapeutic agent to a cerebrospinal fluid of a patient; and
an injectable gabapentin composition housed in the reservoir and deliverable through the catheter in an amount effective to a gabapentin-sensitive disorder in the patient, wherein
the injectable gabapentin composition comprises gabapentin, a pharmacologically acceptable solvent, and less than 0.9% (w/v) sodium chloride.
37. (Original) The system of claim 36, wherein the injectable gabapentin composition is a solution.
38. (Original) The system of claim 37, wherein the solution comprises greater than about 30 mg/ml gabapentin.
39. (Original) The system of claim 38, wherein the solution comprises between about 30 mg/ml and about 100 mg/ml gabapentin.

40. (Original) The system of claim 39, wherein the solution comprises about 80 mg/ml gabapentin.
41. (Original) The system of claim 36, wherein the injectable gabapentin composition further comprises one or more additional therapeutic agents.
42. (Original) The system of claim 41, wherein at least one of the one or more additional therapeutic agents is selected from the group consisting of:
a local anesthetic, a GABA agonist, a serotonin agonist, a thyrotropin-releasing hormone, a benzodiazapine, an opioid agonist, a non-steroidal anti-inflammatory agent, an alpha2-adrenergic agonist, an anticonvulsant agent, and an antidepressant.
43. (Original) The system of claim 41, wherein at least one of the one or more additional therapeutic agents is selected from the group consisting of:
morphine, hydromorphone, bupivacaine, clonidine, lidocaine, baclofen, muscimol, sumatriptan, sodium valproate, midazolam, adenosine, and alprazolam, or a pharmacologically acceptable salt thereof.
44. (Original) The system of claim 43, wherein at least one of the one or more additional therapeutic agents is selected from the group consisting of morphine and hydromorphone, or a pharmacologically acceptable salt thereof.
45. (Original) A method of preparing a system of claim 1, comprising:
adding the injectable gabapentin composition to the reservoir.
46. (Original) A method of preparing a system of claim 36, comprising:
adding the injectable gabapentin composition to the reservoir.
47. (New) The system of claim 1, wherein the injectable gabapentin composition is a sterile composition.

48. (New) The system of claim 47, wherein the composition is sterilized by a process comprising heat-treatment.